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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,779	01/03/2001	Jean-Louis Ruelle	BM45311	5330

25308 7590 09/20/2002

DECHERT
ATTN: ALLEN BLOOM, ESQ
4000 BELL ATLANTIC TOWER
1717 ARCH STREET
PHILADELPHIA, PA 19103

EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	11

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/674,779	Applicant(s) RUELLE, JEAN-LOUIS	
	Examiner Padmavathi v Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-29,31,34,35,53 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-29,31,34,35,53 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election of Group I claims 27-39, 53 and 54 (polypeptide) with respect to SEQ.ID.NO: 2 in Paper No. 10 without traverse is acknowledged. Claims 30, 32, 33, 36-39, 40-52 and 55-61 have been canceled. Claims 27-29, 31, 34, 35, and 53--54 are pending in the application.

Priority

2. This application is a 371 OF PCT/EP 99/03038, 05/3/1999, which claims priority under 35, U.S.C. 119 (a)- (d) U.K 9809683.7, 05/06/1998 is acknowledged. Examiner has reviewed all the priority documents and found that the SEQ.ID.NO: 2 containing 250 amino acids in the present application was not disclosed in the priority documents, PCT/EP 99/03038 and U.K 9809683. It is noted that both documents disclose an amino acid sequence SEQ.ID.NO: 2 containing 172 amino acids. Therefore, the SEQ.ID.NO: 2 of the present application is not the same as the SEQ.ID.NO: 2 of the priority documents, PCT/EP 99/03038 and U.K 9809683.7. Therefore, this application gets priority as of filing date **1/3/2001 of** the current application for claims 27-29, 31, 34, 35, and 53—54 with respect to SEQ.ID.NO: 2

Information Disclosure Statement

3. The Information Disclosure Statement has not been filed in this application.

Specification - Informalities

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF processed by the Scientific and Technical Information Center (STIC) contains only 4 sequences

and is identified as SEQ.ID.N0: 1-4. The specification and the paper copy submitted by the applicant contain 14 sequences, SEQ.ID.NO: 1-14. Therefore, the paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

There is no brief description of the drawing as set forth in 37 C.F.R.1.74.

It is noted that Abstract of the Disclosure is missing. If applicant desires to include the abstract from PCT/EP 99/03038, the Office would consider and a copy of the abstract will be inserted in to the specification.

Claim Rejections - 35 USC 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 53-54 and the dependent claim 27 (as a vaccine composition only) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The definition of "vaccine" is broad, it is not so broad to cover **any** use of a substance on or in the body of a subject, only those uses intended to prevent, treat, or cure a disease within the animal to which the substance was administered.

Enablement of a "vaccine composition" is considered to rest on a teaching of in vivo administration for purposes consistent with the intended use disclosed in the specification. The disclosed intended use for the claimed vaccine is for the treatment of otitis media and respiratory disease caused by Moraxella catarrhalis infections. Thus, the nature of the invention is a therapeutic composition used in the treatment or prevention. In the instant application, the animal to which the claimed composition is administered is merely being used as a bioreactor to make the antibodies (example 5) that will ultimately be used *in vitro*. In addition, the instant specification does not teach how to use the composition, without undue experimentation, for the prevention, treatment, or cure of a disease in the animal to which the substance is administered.

The specification discloses the claimed composition as an immunogen (pages 67-68) and formulating the compositions in Freund's adjuvant. In the instant application, the animal to which the claimed composition is administered is merely being used as a bioreactor to make the antibodies (example 5), there is insufficient guidance which would enable one skilled in the art to use the claimed compositions for their intended purpose, viz., for the generation of a protective immune response against otitis media and respiratory disease caused by Moraxella catarrhalis infections. At the time the invention was made, vaccines comprising the claimed polypeptide were not routinely used for the treatment of otitis media and respiratory diseases. The specification lacks guidance by way of general methods or working examples which teach an "effective amount" of the vaccine which would be used for this purpose. Lack of working examples is given added weight in cases involving an unpredictable and undeveloped art, such as immunotherapy of otitis media and respiratory diseases It is unpredictable whether the

claimed composition which is disclosed as being only immunogenic, would have the added property of generating the protective immune response sufficient to inhibit the otitis media and respiratory diseases because the prior art discloses that vaccine development is at the antigen identification stage and testing of these protective antigens is by testing them in animal models or clinical testing of these antigens (see review article by McMichael , 2000, Microbes and Infection 2; 561-568) The specification has not disclosed a link or nexus between the generation protective antibodies and its use in the above disorders. Further, it is not routine in the art of immunotherapy to use the claimed compositions for this purpose. Accordingly, there is no objective basis upon which the skilled artisan would reasonably be able to determine or predict an amount of the claimed composition/vaccine effective for its intended use. Therefore, undue experimentation would be required to make and use the invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 27-31, 34, 35 and 53-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is rejected as being vague and not clear in reciting " T-cell immune response to a polypeptide having the sequence of SEQ.ID.NO: 2." It is not clear what T-cell immune response applicant intend to mean. Does applicant intend to mean T-cell mediated immune response which induces TH1 or TH-2 cytokine dependent immune response or something else? And also it is not clear whether T-cell mediated response is to the polypeptide SEQ.ID.NO: 2 or something less than a polypeptide SEQ.ID.NO: 2 since the claim recites "a polypeptide".

Claim 54 is rejected for the recitation of " one other M.catarrhalis antigen". It is difficult to understand the metes and bounds of one other M.catarrhalis antigen as written.

Applicant is advised to amend the claims to recite only SEQ.ID.NO: 2 since this is an elected invention.

Claim Rejections - 35 USC 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 27-29, 31 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Helminen et al 1994 (J.Infec.Dis, 170; 867-872).

Claims are directed to an isolated polypeptide comprising (a) an amino acid sequence matching SEQ.ID.NO: 2 (b) an immunogenic polypeptide comprising a fragment of SEQ.ID.NO: 2 where in the polypeptide, when administered with a carrier induces an antibody response.

Helminen et al 1994 discloses an isolated polypeptide, outer membrane protein i.e., OMP from whole cell lysate of M.catarrhalis. Monoclonal antibodies were produced by administering (i.e., immunizing) whole cell lysate antigens to mice (page 867, right column through page 868, left column, first paragraph). Applicant's use of the open-ended term "comprising " in the claims 27-29 and 31 fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed isolated polypeptide, OMP from M.catarrhalis. Whole cell lysates from M.catarrhalis inherently comprise the amino acid sequence as set forth in the SEQ.ID.NO: 2 and fragments of SEQ.ID.NO: 2. See In re Horvitz, 168 F 2d 522, 78

U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art protein and the claimed isolated polypeptide comprising (a) an amino acid sequence matching SEQ.ID.NO: 2 are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ.ID.NO: 2 with the polypeptide of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

11. Claims 27-29, and 31 ~~and 34~~ are rejected under 35 U.S.C. 102(a) as being anticipated by Legace et al 2000 WO 0078968: pages 87-88 (Examiner is enclosing only pages 87-88 from the Patent WO 0078968: as the patent is length containing 456 pages).

Claims are directed to an isolated polypeptide comprising a member selected from the group consisting of an (a) an amino acid sequence matching SEQ.ID.NO: 2 (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2, where in the isolated polypeptide induces an antibody or T-cell immune response.

Legace et al disclose an isolated polypeptide (see claim 10, pages 87-88) encoded by polynucleotide from position 11483-12232 comprising an amino acid sequence matching SEQ.ID.NO: 2 (see the attached reverse translation of the disclosed polynucleotide from positions 11483-12232 of SEQ.ID.NO: 17). The disclosed polypeptide is 100% identical to SEQ.ID.NO: 2. Further, the prior art discloses an isolated polypeptide comprising15 amino acid contiguous segment of SEQ.ID.NO: 2. The prior art anticipated the claimed invention.

The art teaches that an immunogenic fragment (i.e., antigen or epitope) is roughly 5 amino acids in size (Levinson et al Medical Microbiology & Immunology 1994, page 293) and an

antigen can have one or more determinants (i.e., epitopes). Epitopes can elicit an immune response and react with an antibody. Therefore, Legace et al meet the limitations (i.e., peptide comprising at least 15 amino acids) of the claims.

Status of Claims

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

9/14/02

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600